

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Status of Claims:

Pursuant to the restriction requirement made by the examiner, claims 1-41 and 49-52 are withdrawn. By the present Amendment, claim 42 is amended and new claims 56-58 are added. Thus, claims 1-58 are pending, while claims 42-48 and 53-58 are under consideration.

However, Applicant respectfully traverses the Examiner's withdrawal of claims 1-41 and requests examination of those claims. While the Examiner argued that claims 1-41 are not generic to the non-elected embodiment I (Fig. 1) and the elected embodiment II (Fig. 2), those claims would at least read on embodiment II (Fig. 2).

In particular, as pointed out in Applicant's response to the Restriction requirement, claims 1 (and, thus, dependent claims 2-25) recite, among other features, "a plurality of implantable sensing elements, each implantable sensing element of the plurality of implantable sensing element is operable through electrical communication with an external controller via an individual interconnect." It is respectfully submitted that such a configuration is either generic to both embodiments I and II (Figs. 1 and 2, respectively) or reads on the elected embodiment of Fig. 2 (which shows individual conductors connected to each sensing element, for communication with an external controller).

Similarly, claim 26 refers to, among other features, "a plurality of implantable sensing elements, each implantable sensing element of the plurality of implantable sensing elements operable through electrical communication with an external controller via an individual interconnect." Like claim 1, claim 26 also refers to an individual interconnect. That configuration is either generic to both embodiments I and II (Figs. 1 and 2, respectively) or reads on the elected embodiment of Fig. 2 (which shows individual conductors connected to each sensing element, for communication with an external controller).

Accordingly, claims 1-41 are believed to be in the elected embodiment and examination of those claims is requested.

Claim Rejections:

Claims 42 and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarantino et al. (PCT W)2001/22874) (hereinafter Scarantino).

With regard to the rejection of claim 42, this rejection is respectfully traversed.

Independent claim 42, recites a method of sensing multiple parameters, the method comprising:

- implanting an implantable sensor at a single site in a patient, the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements; and
- reading an output from at least one implantable sensing element of the plurality of implantable sensing elements,
 - wherein each implantable sensing element of the plurality of implantable sensing elements comprises a respective power supply, wherein the power supply for each implantable sensing element is configured to supply power independent of the power supply for each other implantable sensing element;
 - wherein a plurality of parameters are read from the implantable sensor at the single site, and
 - wherein the output read from said at least one implantable sensing element of the plurality of implantable sensing elements is a quantifiable value.

Scarantino neither teaches nor suggests a method of sensing multiple parameters as recited in claim 42, including implanting an implantable sensor having a housing within which are disposed a plurality of implantable sensing elements, wherein each implantable sensing element of the plurality of implantable sensing elements comprises a respective power supply, wherein the power supply for each implantable sensing element is configured to supply power independent of the power supply for each other implantable sensing element.

Instead, Scarantino describes embodiments in which sensor elements 51 of a sensor unit 50 are powered by a common power source (not be a respective power supply configured to supply power independent of the power supply for each other implantable sensing element in a

housing) or other embodiments in which dependent sensor units 50D are inductively coupled to a satellite sensor unit 50S, which is, in turn, inductively powered to an external system (not by a respective power supply that is independent of the power supply for each other implantable sensing element in a housing).

More specifically, Scarantino shows various embodiments of sensor units, including an embodiment in Scarantino's Figure 5, which "shows a sensor unit 50' with one sensor element 51" and an embodiment in Figure 6a, which "shows a sensor unit 50 with a plurality of sensor elements 51a-51c." (Scarantino, pg. 27, ll. 21-25.) In Figs. 5 and 6A, the sensor unit 50', 50, includes a main body portion 50B (Fig. 6A) and one arm (Fig. 5) or a plurality of arms (Fig. 6A) extending outward from the main body 50B. One or more sensor elements 51 are positioned on each arm and are electrically connected through electrical leads in the arm to electronic operating circuitry 125 in the main body 50B. (Scarantino, pg. 28, ll. 6-15.) In Figure 5, Scarantino shows a single battery 52 connected, through the SMT electronics 125, as the only power supply. (Scarantino, Fig. 5 and pg. 36, ll. 37-38.)

Because the sensor unit 50', 50 in Figs. 5 and 6A of Scarantino employ a single power source, Scarantino does not disclose or suggest a method including implanting an implantable sensor having a housing within which are disposed a plurality of implantable sensing elements, wherein each implantable sensing element comprises a respective power supply and wherein the power supply for each implantable sensing element is configured to supply power independent of the power supply for each other implantable sensing element. Accordingly, claim 42 is patentably distinguished from the embodiment of Figs. 5 and 6 of the Scarantino reference.

Scarantino also describe an injectable sensor unit 50I with reference to Figs. 7, 8A and 8B of the Scarantino reference. The injectable sensor unit 50I (or the implantable version 50 discussed above) can be "inductively powered," where "the monitoring system is configured to act as a transformer ... to couple and power the internally disposed sensors ..." (Scarantino, pg. 29, ll. 16-21.) In a "hybrid" embodiment of Fig. 9 of the Scarantino reference, Scarantino describes a sensor unit 50''' as including a satellite sensor unit 50S with the IC or externally communicating electronics 125 thereon and a plurality of dependent sensor units 50D. The

dependent sensor units 50D are inductively coupled to the satellite sensor unit 50S which is, in turn, inductively powered and coupled to the external system. (Scarantino, pg. 30, ll. 1-8.)

In the inductively powered embodiments of the Scarantino reference, the main (or satellite) sensor unit receives inductive power and, in turn, provides power to either sensor elements (51 in Fig. 6A) or dependent sensor units (50D in Fig. 9). Because the sensor elements (51 in Fig. 6A) and dependent sensor units (50D in Fig. 9) receive power from a common power source, through the main (or satellite) sensor unit 50B, 50I, there is no independent power supplies (independent of the power supply of each other implantable sensing element). Accordingly, Scarantino's inductive or hybrid embodiments also do not disclose or suggest a method including implanting an implantable sensor having a housing within which are disposed a plurality of implantable sensing elements, wherein each implantable sensing element comprises a respective power supply and wherein the power supply for each implantable sensing element is configured to supply power independent of the power supply for each other implantable sensing element. Therefore, claim 42 is patentably distinguished from the inductive and hybrid embodiments described by Scarantino, including the embodiments of Figs. 7-9 of the Scarantino reference. The rejection of claim 42 is, therefore, respectfully traversed.

As discussed above, claim 42 is patentably distinguished from the Scarantino reference. As claims 54 and 55 are each dependent on claim 42, the rejection of those claims is respectfully traversed at least for reasons discussed above with respect to claim 42 and further reasons apparent from the language of claims 54 and 55. The rejection of claims 54 and 55 is, therefore, respectfully traversed.

Claims 43-47 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sacrantino et al. in view of Natarajan et al. U.S. Patent 6,501,983.

With regard to the rejection of claim 43, this rejection is respectfully traversed.

Claim 43 defines a method of sensing multiple parameters, the method comprising:

implanting an implantable sensor at a single site in a patient, the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements, each implantable sensing element of the plurality of implantable sensing

elements operable through electrical communication with an external controller via a respective individual interconnect of a plurality of individual interconnects, each implantable sensing element of the plurality of implantable sensing elements allowing for sensing at least one of a respective biological parameter, a respective physiological parameter, and a respective analyte; and

reading an output from at least one implantable sensing element of the plurality of implantable sensing elements,

wherein a plurality of parameters are read from the implantable sensor at the single site,

wherein the output read from said at least one implantable sensing element of the plurality of implantable sensing elements is a quantifiable value, and

wherein the plurality of implantable sensing elements comprises a lactate sensing element measuring a parameter for blood lactate level, a blood oxygen saturation sensing element measuring a parameter for blood oxygen level, and a pH level sensing element measuring a parameter for pH level (emphasis added).

Scarantino neither teaches nor suggests a method of sensing multiple parameters, including implanting an implantable sensor at a single site in a patient, where the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements, and were each implantable sensing element of the plurality of implantable sensing elements operable through electrical communication with an external controller via a respective individual interconnect of a plurality of individual interconnects.

Instead, in Fig. 6, Scarantino describes sensor unit 50 that has a primary body portion 50B and arm portions 50A, where sensor elements 51 are disposed on the arm portions with electrical connections to electronics in the main (or primary) body portion 50B, but with no disclosed electrical communication with an external controller through individual interconnects. Instead, the electronics in the primary body portion 50B has a single transmitter coil 58 for electrical communication with an external communication. Thus, in Scarantino's Fig. 6 embodiment, the sensor elements 51 are not in a common housing with the main (or primary) body portion 50B and are not individually connected (through individual interconnects) to an external controller.

Furthermore, because Scarantino uses single transmitter coil 58 for all of the sensor elements connected to the primary body portion 50B (instead of individual interconnects to an external controller), the communication signals from all of Scarantino's sensor elements 51 have to go through the telemetry link 60, one at a time to make communications with external devices

such as the bedside unit and the laptop computer. In other words, in Scarantino, while the data may be gathered in parallel from the sensor units 51, the data for each sensor must nevertheless go out one at a time and serially because there is no individual interconnects for communication to the external devices from the sensor elements 51.

Similar comments apply to Scarantino's Fig. 7 embodiment, wherein the sensor elements 51 are within an injectable unit 50I, but otherwise are not connected through individual interconnects to an external controller.

In the hybrid embodiment of Fig. 9, dependent sensor units 50D and a satellite sensor unit 50S are inductively coupled. However, because each unit 50D and 50S are separate, but inductively coupled, Scarantino's embodiment of Fig. 9 does not include a implanting an implantable sensor at a single site, where the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements, and where each implantable sensing element is operable through electrical communication with an external controller via a respective individual interconnect.

Accordingly, it is respectfully submitted that claim 43 is patentably distinguished over the Scarantino reference.

Natarajan does not teach or suggest the above mentioned distinctions between claim 43 and the Scarantino reference. Instead, the Examiner had cited Natarajan as disclosing a lactate sensing element and a blood oxygen saturation sensing element. Natarajan shows how a plurality of devices may be used to gather and interpret data from within the heart, from the heart surface, and/or from the thoracic cavity.

Therefore neither Scarantino nor Natarajan individually or in combination with one another teach or suggest the above mentioned distinction. As such, claim 43 is patentable over Scarantino, in view of Natarajan and the rejection of claim 43 is respectfully traversed.

Claims 44-47 and 53 are each dependent (directly or indirectly) on claim 43 and are believed to be in condition for allowance at least for reasons as discussed above with respect to

claim 43 and further reasons apparent from the language of claims 44-47 and 53. Accordingly, the rejection of claims 44-47 and 53 is also respectfully traversed.

Claims 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scarantino et al. and Natarajan, and further in view of Polaschegg et al. U.S. Patent 4,844,871.

With regard to the rejection of claim 48, this rejection is respectfully traversed.

Claim 48 is dependent on claim 43, and as such is patentable over Scarantino in view of Natarajan, at least for the same reasons and distinction explained above with respect to claim 43. Furthermore, Polaschegg does not address the above mentioned distinctions between claim 43 and the Scarantino and Natarajan references. Instead, the Examiner cited the Polaschegg reference as describing ECMO therapy.

Accordingly, the rejection of claims 48 as being unpatentable over Scarantino et al. in view of Natarajan, and further in view of Polaschegg is respectfully traversed.

New claims 56-58 are added to further protect aspects of the claimed invention. New claims are supported by the original application, at least with respect to paragraphs 0033 and 0037. New claims 56-58 are each dependent on claim 42 and are further distinguished from the references of record. New claim 56 recites that each implantable sensing element is electrically connected to an electrical conductor that extends out of the housing. New claim 57 recites that each implantable sensing element is electrically connected to an electrical conductor that is electrically connectable to a remote device outside of the housing. New claim 58 recites that each implantable sensing element is electrically connected to an electrical conductor that is electrically connectable to a controller.

Conclusion:

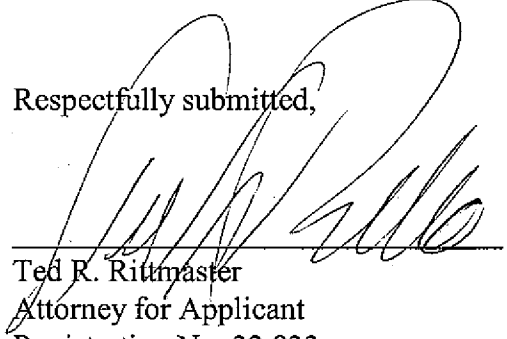
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

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